Remarks

Reconsideration of this Application is respectfully requested. Applicants thank the Examiner for the allowance of claims 3-5.

Upon entry of the foregoing amendments, claims 2-14 and 24-28 are pending in the application, with claims 2, 4, 8 and 27 being the independent claims. Claims 1 and 15-23 are sought to be cancelled without prejudice to or disclaimer of the subject matter therein. New claims 24-28 are sought to be added. Support for the foregoing amendments to the claims may be found in the original claims as filed and throughout the specification. Specifically, support for amendment to claim 2 may be found at page 9, lines 1-22. Allowed claim 4 was amended to render it independent of claim 1. Allowed claims 3 and 5 are now dependent on claims 4 and 3, respectively. Claims 6, 7, 11 and 12, all previously dependent on claim 1, were amended to change their dependency to claim 2. New claims 24-26 are identical to claims 11-13 except for their dependencies. New claim 27 has been newly added to more specifically cover the coding sequence region of the nucleotide sequence of SEQ ID NO:6. New claim 28, which is related to claim 5, for example, covers the amino acid sequence encoded by the polynucleotide sequence of claim 27. Support for claims 27 and 28 can be found throughout the specification, for example at page 17, line 26; at page 18, lines 13-20; in the Sequence Listing; and in Figures 1 and 5. These changes are believed to introduce no new matter, and their entry is respectfully requested.

Based on the above amendment and the following remarks, Applicant respectfully requests that the Examiner reconsider all outstanding rejections and that they be withdrawn.

Rejection under 35 U.S.C. § 112, Second Paragraph

In the Office Action at page 2, the Examiner has rejected claim 2 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Applicant respectfully traverses this rejection.

The Examiner states that the "[r]ecitation of 'complementary' is indefinite, as the phrase 'complementary' can mean a polynucleotide complementary to a small region of a given DNA or alternatively complementing the entire region." Office Action at page 2. Solely to advance prosecution and not in acquiescence of the Examiner's rejection, Applicant has recited "completely complementary" as suggested by the Examiner. Accordingly, reconsideration and withdrawal are respectfully requested.

Rejections under 35 U.S.C. § 112, First Paragraph

A. Written Description

In the Office Action at page 2, the Examiner has rejected claims 2 and 6-7 under 35 U.S.C. § 112, first paragraph, as allegedly lacking written description and failing to provide the appropriate evidence of satisfying the deposit of the polynucleotide clone for the enforceable life of the patent. Applicant respectfully traverses this rejection.

Applicant advises that all restrictions imposed by the Depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent issuing from the instant application. Applicant further advises that the deposit of the polynucleotide clone will be satisfied by Applicant for the enforceable life of the patent. Accordingly, reconsideration and withdrawal are respectfully requested.

B. Enablement

In the Office Action at pages 2-4, the Examiner has rejected claim 2 under 35 U.S.C. § 112, first paragraph, as allegedly non-enabled. Applicant respectfully traverses this rejection.

The Examiner states that while the specification is

> enabling for an isolated nucleic acid molecule comprising a nucleotide sequence encoding a PCA3 polypeptide of SEQ ID NO:2, 7 and clones of accession number CBS 682.97 and CBS 100521, does not reasonably provide enablement for an isolated nucleic acid molecule comprising of a nucleotide sequence that is at least 90% identical to SEQ ID NO:2, 7, clones of accession number CBS 682.97 and CBS 100521, and a sequence complementary to any of sequence in (a)-(d).

Office Action at pages 2-3. Solely to advance prosecution and not in acquiescence of the Examiner's rejection, Applicant has deleted the terminology and recites terminology relating to hybridization conditions. Applicants reserve the right to prosecute claims comprising the "90% identical" terminology in further applications. Accordingly, reconsideration and withdrawal is respectfully requested.

Rejections under 35 U.S.C. § 102

In the Office Action at pages 4-5, the Examiner has rejected claims 1 and 8-14 under 35 U.S.C. § 102 as allegedly anticipated by Bussemakers *et al.*, 87th Annual Meeting of the American Association for Cancer Research, Washington, DC, April 20-24 (1996) (Doc. X1 in PTO-892 of Paper No. 17; hereinafter "Bussemakers"). Applicant respectfully traverses this rejection.

Bussemakers does *not* teach *any* sequence nor does it characterize the genomic structure of DD3. Furthermore, Bussemakers teaches in lines 5-6 that:

> [n]ucleotide sequence analysis of DD3 did *not* reveal an open-reading frame . . .

Bussemakers at page 1 (emphasis added). Bussemakers further teaches the complexity of the region by stating that:

> [a]lternative splicing *may* occur.

Id. (emphasis added).

In addition, the uncertainty in the teachings of Bussemakers are emphasized by the statement that:

> in the human prostate cancer cell lines LNCaP, Du145, PC3 and TSU, no DD3 transcripts could be detected. We are *currently investigating whether* we can use RT-PCR analysis of DD3 to detect prostate cancer cell in the peripheral blood of patients. Furthermore, *we will try* to gain insight in the function of DD3 and its role in prostate cancer development.

Id. (emphasis added).

In view of the above, and especially in view of the fact that in Bussemakers, the nucleotide sequence of DD3 is neither taught nor suggested, and that DD3 did not reveal an open-reading frame, Applicant respectfully requests that the Examiner withdraw the rejection of claims 1, 8-14 as being anticipated by Bussemakers.

Conclusion

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. Applicant believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that

personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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Version with markings to show changes made

(a) Claims 1 and 15-23 have been cancelled.

(b) Claims 24-28 are sought to be added.

(c) Claims 2-7 and 11-12 are amended as follows:

2. (Once Amended) [The isolated nucleic acid molecule according to claim 1] An isolated nucleic acid molecule encoding prostate cancer antigen 3 (PCA3) comprising a polynucleotide sequence selected from the group consisting of:

(a) a nucleotide sequence encoding a PCA3 polypeptide comprising the complete amino acid sequence in SEQ ID NO:2;

(b) a nucleotide sequence encoding a PCA3 polypeptide comprising the complete amino acid sequence in SEQ ID NO:7;

(c) a nucleotide sequence encoding a PCA3 polypeptide comprising the complete amino acid sequence encoded by the polynucleotide clone contained in the deposit at the Centraal voor Schimmelcultures as accession number CBS 682.97;

(d) a nucleotide sequence encoding a PCA3 polypeptide comprising the complete amino acid sequence encoded by the polynucleotide clone contained in the deposit at the Centraal voor Schimmelcultures as accession number CBS 100521;

(e) a nucleotide sequence comprising the nucleotide sequence set forth in SEQ ID NO:1, 3, 4, or 6;

[(e)] (f) a nucleotide sequence completely complementary to any of the nucleotide sequences in (a), (b), (c), [or] (d) or (e); and

[(f)] (g) a nucleotide sequence which hybridizes under high stringency

conditions to any of [he] the nucleotide sequences in (a), (b), (c), (d), [or] (e) or (f).

3. (Once Amended) The isolated nucleic acid molecule according to claim [1] 4, wherein the molecule comprises the nucleotide sequence encoding PCA3 as set forth in SEQ ID NO:1 or 6.

4. (Once Amended) [The isolated nucleic acid molecule according to claim 1] An isolated nucleic acid molecule encoding prostate cancer antigen 3 (PCA3) comprising the nucleotide sequence set forth in SEQ ID NO:1, 3, 4, or 6.

5. (Once Amended) The isolated nucleic acid molecule according to claim [1] 3, wherein the molecule encodes the polypeptide comprising the complete amino acid sequence set forth in SEQ ID NO:2 or 7.

6. (Once Amended) The isolated nucleic acid molecule according to claim [1] 2, wherein the nucleotide sequence encoding a PCA3 polypeptide comprises the complete amino acid sequence encoded by the polynucleotide clone contained in the deposit at the Centraal voor Schimmelcultures as accession number CBS 682.97, respectively.

7. (Once Amended) The isolated nucleic acid molecule according to claim [1] 2, wherein the nucleotide sequence encoding a PCA3 polypeptide comprises the complete amino acid sequence encoded by the polynucleotide clone contained in the deposit at the Centraal voor Schimmelcultures as accession number CBS 100521, respectively.

11. (Once Amended) A recombinant nucleic acid molecule comprising, 5 to 3 , a promoter effective to initiate transcription in a host cell and the nucleic acid molecule according to claim [1] 2.

12. (Once Amended) A recombinant nucleic acid molecule comprising a vector and the nucleic acid molecule according to claim [1] 2.